



# MassBiologics

Medicine for Better Lives



October 1, 2017

Honorable Steven T. James  
Clerk of the House of Representatives  
Room 145  
State House  
Boston, MA 02133

Honorable William F. Welch  
Clerk of the Senate  
Room 335  
State House  
Boston, MA 02133

Dear Mr. James and Mr. Welch:

As required by Chapter 75, Section 43(f), we are pleased to "submit to the Clerks of the Senate and the House of Representatives, a report of the activities of Mass Biologics within ninety days after the end of the fiscal year." This is the twenty-first year of such annual reports required by the legislation, which transferred MassBiologics from the Department of Public Health to the University of Massachusetts.

If you have any questions, please contact Chris Kelberman, MassBiologics. 460 Walk Hill St., Boston, MA 02126, (617) 474-3016.

Sincerely,

Michael F. Collins, M.D.  
Chancellor  
University of Massachusetts Medical School

Mark S. Klempner, M.D.  
Executive Vice Chancellor, MassBiologics  
University of Massachusetts Medical School

SD2354

**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS  
FISCAL YEAR 2017**

**AS REQUIRED BY CHAPTER 75, SECTION 43(F)**

**SUBMITTED TO  
CLERK OF THE HOUSE OF REPRESENTATIVES**

**&**

**CLERK OF THE SENATE**

**October 1, 2017**

**BY**

**MASSBIOLOGICS of the  
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**

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## **1. INTRODUCTION**

This report is submitted, as required by Chapter 75, Section 43(f), on the activities of the MassBiologics of the University of Massachusetts Medical School. This is the twenty-first year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY17) Information, as indicated by legislation, describes the patents and licenses, agreements entered into, status of existing agreements, royalties and other benefits, and expenditures, current assets and liabilities. This section includes two schedules: (1) FY17 Balance Sheet and (2) FY17 Statement of Revenues and Expenditures and Other Charges. Included here is information related to appropriated funds for the prior fiscal year, as required by the legislation.

Part 3, Financial Plans, presents projected revenues and expenses. A three-year projection is included.

## **2. PRIOR FISCAL YEAR (FY17) INFORMATION**

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY17: July 1, 2016 - June 30, 2017). This is the twenty-first full year in which MassBiologics has operated within the University of Massachusetts. The effective date of the transfer to the University of Massachusetts was January 1, 1997.

### **a. Patents and Licensing**

MassBiologics had two patents with claims allowed in FY17:

Title: Antibodies Against Clostridium Difficile Toxins and Uses Thereof

- Norway – Patent No. 340300 Issued March 27, 2017

Title: Anti-SOD1 Antibodies and Uses Thereof

- United States – Patent No. 9,663,586 Issued May 30, 2017

### **b. Agreements entered into**

MassBiologics extended its exclusive distribution agreement with Grifols Worldwide Operations Ltd. for the distribution of Tetanus and Diphtheria vaccine for a two year term ending June 30, 2019.

MassBiologics entered into a non-exclusive license agreement with Antigen Pharmaceuticals Inc. for monoclonal antibodies for the treatment of diphtheria October 1, 2016.

MassBiologics entered into a commercialization agreement with Adimab LLC for the commercialization of therapeutic ebola antibodies effective May 2, 2017.

MassBiologics entered into a series of research and collaboration agreements as follows:

- 1) University of Maryland for research into therapeutic antibodies for ETEC, effective August 8, 2016.
- 2) University College London, for research into novel treatment for chronic granulomatous disease effective April 24, 2017.
- 3) Sixal Inc. for studies into antibody binding effective May 10, 2017.
- 4) University of Virginia for studies into ETEC, effective July 12, 2017.

MassBiologics' contract development and manufacturing services enjoyed strong growth in FY17. Highlights include: addition of 4 new clients utilizing services originating in the Mattapan Facility; bio manufacturing capacity at Mattapan booked at 100% capacity through December 2018; completion of South Coast Vector Manufacturing Center "VMC" GMP manufacturing facility validations and the production of its first lot of cGMP clinical material;

a second VMC client was signed, for whom we will be manufacturing commercial supplies of a viral vector therapy for an ultra-orphan neurological disease; one hundred new service agreements were executed in FY17 representing \$22.2M in sales and generating \$15.4M in revenue.

**c. Grants and Contracts Awarded**

DARPA – A no cost extension was received on Award of \$11,411,276 from Defense ADV Research Projects Agency through December 31, 2017. \$4,422,355 of funding was received in FY17.

Gates Foundation – Award of \$1,967,060 was received from Bill and Melinda Gates Foundation effective May 4, 2017 through December 31, 2018. \$54,034 of funding was received in FY17.

NIH Contract – Award of \$5,328,431 was received from NIH-Nat'l Inst. Of Allergy & Infectious Disease effective September 29, 2013 through September 28, 2016. \$469,889 of funding was received in FY17.

U24 Grant – Award of \$8,645,123 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective September 29, 2016 through May 31, 2021. \$1,790,832 of funding was received in FY17.

R24 Grant - Award of \$2,837,738 was received from National Institutes of Health effective January 1, 2016 through November 30, 2019. \$545,126 of funding was received in FY17.

NIH Grant – A no cost extension was received on Award of \$1,160,228 from NIH-Nat'l Inst. of Allergy & Infectious Disease through April 30, 2018. An additional Award of \$56,133 was received. \$302,997 of funding was received in FY17.

NIH Grant – Award of \$173,987 was received from NIH-Nat'l Inst. of Neurological Disorders and Stroke effective September 20, 2015 through August 31, 2017. \$86,244 of funding was received in FY17.

CTR Advancing Translational Sciences – Award of \$288,262 was received from NIH-Nat'l Ctr Advancing Transitional Sciences effective August 14, 2015 through March 31, 2019. \$214,724 of funding was received in FY17.

CDC Contract – Award of \$228,946 was received from Antigen Pharmaceuticals, Inc. effective September 30, 2015 through September 29, 2017. \$106,585 of funding was received in FY17.

UCSF Grant – Award of \$675,488 was received from University of California San Francisco effective July 16, 2016 through June 30, 2021. \$229,438 of funding was received in FY17.

MGH Grant – An award of \$406,345 was received effective December 1, 2016 through October 31, 2018. \$84,752 of funding was received in FY17.

**d. Status of existing agreements, royalties and other benefits**

MassBiologics had the following major existing agreements in FY17.

Bristol-Meyers Squibb, formerly Medarex - a collaborative development agreement had previously been signed April 17, 2002 with a public company (Medarex). This agreement remains in place in support of MassBiologics' continued research.

The Materials Cooperative Research and Development Agreement (M-CRADA) that was entered into January 30, 2004 with the CDC for Rabies was extended until January 30, 2006. Subsequently, that agreement evolved into an Inter-institutional Agreement that was executed in August 2005.

Merck Exclusive License Agreement April 20, 2009 for antibodies against C. Difficile. This agreement remains in place in support of continued clinical development of MassBiologics' proprietary CDiff antibodies.

Serum Institute of India License and Collaboration Agreement effective September 27, 2006. This agreement remains in effect for the development and commercialization of a rabies monoclonal antibody for the treatment of rabies.

Grifols Inc. – Distribution Agreement for Td vaccine in USA and Canada, effective 7/1/2015, as extended.

Voyager Therapeutics Inc. – Strategic Collaboration Agreement for development and manufacturing of adeno associated virus (AAV) products, effective 10/20/2014.

Life Technologies Corporation – Cell Line Services License agreement effective 12/19/2014; Commercial Production License effective 5/1/2015; authorizes use of certain materials to support internal research and for use in services provided to external parties.

Sale of Reagents: Reagents are by-products of the major manufacturing products of MassBiologics. MassBiologics makes these reagents available for research purposes.

**e. Revenues, expenditures, assets and liabilities**

On the pages that follow, please find two schedules: (1) FY17 Statement of Revenues and Expenditures and Other Charges, and (2) FY17 Balance Sheet. This information is reviewed as part of the University of Massachusetts annual audit and is included as part of comprehensive financial reports made to the University of Massachusetts' Board of Trustees. Financial activities are also reported to the Office of the State Comptroller which is still in process for FY 2017.

When reviewing these schedules, please note:



- State Appropriations / DPH represents the DPH appropriated fund support of the effort at the Biologic Laboratories of \$782,276. These funds only partially support staff and provide the supplies and equipment used in the production of vaccine which is distributed to residents of Massachusetts without charge. The vaccine that is provided is Tetanus-Diphtheria vaccine (Td).
- License and Royalty Fees represents such payments received for CMV-IGIV, and monoclonal antibodies to RSV and *C. difficile*.

The Plant Fund is to cover the replacement of major equipment, essential facility improvements necessary to meet FDA and other manufacturing license requirements. This account includes the cumulative capitalized equipment purchases and building improvements and a balance of unexpended funds in reserve for planned equipment purchases and building improvements. In FY17, the plant fund continued to also be used to conclude the new facility expenses.

The core activities of MassBiologics remained consistent though FY17.

In calendar year 2008, the MassBiologics received its licensure from the FDA to bring its new production facility on line. MassBiologics continued to manufacture clinical material in the new facility to support its IND activities.

The new production facility is located at the old Boston State Hospital location. This location was authorized by the legislature in July 2000 and opened October 2005. To support the costs of the new facility, Worcester City Campus Corporation borrowed in FY02 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of MassBiologics. The plant fund represents payment of the lease payments supporting the bonds, as well as other capital costs associated with Worcester City Campus Corporation, the University of Massachusetts Medical School and the capital needs and operations of MassBiologics.

Construction of Mattapan II was completed in the late spring of 2010. The project was on time and within budget. Mattapan II was also occupied in this timeframe.

To support the costs of Mattapan II, Worcester City Campus Corporation borrowed \$35 million in FY07 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of the MassBiologics.

It was determined that MassBiologics would benefit from consolidating its operations to one campus by making facilities modifications to the Mattapan Campus. Modifications completed by June 2013 made it possible for MassBiologics to leave the Jamaica Plain Campus effective June 30, ending a 119 year tenancy at that campus. Commissioning and validation activities have been completed and the FDA has inspected and approved the manufacturing of Td vaccine.

In FY15 it was determined that the MAB facility developed under the guidance of the UMass Dartmouth campus would be a better strategic fit if it were configured as a cGMP manufacturing resource for the development of vectored therapeutics under the operational control of MassBiologics. The previously identified grants (from prior year) totaling \$10M



from the MLSC and MassWorks were invested in the facility located at 1240 Innovation Way to support the cGMP requirements of vector manufacturing. In FY16, the initial scope of work was completed on time and on budget with a few areas identified for future projects. The facility is now positioned to develop and manufacture cGMP requirements of vector manufacturing; validation is ongoing.

MassBiologics received a \$2M business loan from the Greater Fall River Development in FY16. Payments will be repaid over a five year term.

In FY17, the outstanding bonds related to the facilities discussed, were refinanced, thereby reducing the future debt service payments.

**University of Massachusetts Biologic Laboratories**  
**Statement of Revenues, Expenditures and Other Changes**  
**For the Period July 1, 2016 Through June 30, 2017**

(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	41,041,272		41,041,272
Restricted Grants and Contracts	8,306,975		8,306,975
State Appropriations/DPH		782,276	782,276
Royalty Fees and Interest	28,776,557		28,776,557
Recovery of Indirect Costs	898,294		898,294
Other Income	1,300,846		1,300,846
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Total Revenue and Other Additions	80,323,944	782,276	81,106,220
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	18,806,948	405,732	19,212,680
Fringe Benefits	5,780,941	114,399	5,895,340
Supplies and Services	41,666,024	262,145	41,928,169
Depreciation	1,542,577		1,542,577
	<hr/>		
Total Expenditures and Other Deductions	67,796,490	782,276	68,578,766
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Net Increase/(Decrease) Before Transfers	12,527,454		12,527,454
Nonmandatory Transfers			
Transfers	2,340,948		2,340,948
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Total Transfers	2,340,948	0	2,340,948
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Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
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NET INCREASE(DECREASE) FOR THE YEAR	14,868,402		14,868,402
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Fund Balances at Beginning of Year (7/1/16)	40,597,634		40,597,634
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FUND BALANCES AT END OF YEAR	55,466,036	0	55,466,036
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(Unaudited)

**University of Massachusetts Biologic Laboratories**

**Balance Sheet**

**As of June 30, 2017**

**(Unaudited)**

	<b>CURRENT FUND FY17</b>	<b>PLANT FUND FY17</b>	<b>TOTAL FY17</b>
<b>Assets</b>			
Cash	12,534,024	9,711,932	22,245,956
Accounts Receivable	13,782,025		13,782,025
Inventory	8,673,303		8,673,303
Prepaid Expenses	111,683		111,683
Buildings & Equipment		14,388,312	14,388,312
Other Assets			
<b>Total Assets</b>	<b>35,101,035</b>	<b>24,100,244</b>	<b>59,201,279</b>
<b>Liabilities</b>			
Accounts Payable	1,755,197	134,960	1,890,157
Employee-Related Accruals	322,530		322,530
Other Liabilities		1,522,556	1,522,556
<b>Total Liabilities</b>	<b>2,077,727</b>	<b>1,657,516</b>	<b>3,735,243</b>
<b>Fund Balances</b>	<b>33,023,308</b>	<b>22,442,728</b>	<b>55,466,036</b>
<b>Total Liabilities and Fund Balance</b>	<b>35,101,035</b>	<b>24,100,244</b>	<b>59,201,279</b>

## Financial Plans

**University of Massachusetts Biologic Laboratories**  
**Statement of Revenues, Expenditures and Other Changes**  
**For the Period July 1, 2017 Through June 30, 2018**

(Unaudited)

	<b>CURRENT FUND</b>	<b>APPROPRIATED FUNDS</b>	<b>TOTAL</b>
<b>REVENUE AND OTHER ADDITIONS:</b>			
Product Sales	30,893,000		30,893,000
Restricted Grants & Contracts	7,809,000		7,809,000
State Appropriations/DPH		516,000	516,000
Royalty Fees and Interest	18,796,000		18,796,000
Recovery of Indirect Costs	1,156,000		1,156,000
Other Income	0		0
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<b>Total Revenue and Other Additions</b>	<b>58,654,000</b>	<b>516,000</b>	<b>59,170,000</b>
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<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
Salaries	19,939,000	390,000	20,329,000
Fringe Benefits	6,353,000	121,000	6,474,000
Supplies and Services	27,210,000	5,000	27,215,000
Depreciation	2,527,000	0	2,527,000
	<hr/>		
<b>Total Expenditures and Other Deductions</b>	<b>56,029,000</b>	<b>516,000</b>	<b>56,545,000</b>
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<b>Net Increase/(Decrease) Before Transfers</b>	<b>2,625,000</b>	<b>0</b>	<b>2,625,000</b>
<b>Nonmandatory Transfers</b>			
<b>Transfers</b>			
	<hr/>		
<b>Total Transfers</b>	<b>0</b>	<b>0</b>	<b>0</b>
	<hr/>		
<b>Other Changes</b>			
Excess of Restricted Receipts over Transfers to Revenue			
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<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	<b>2,625,000</b>		<b>2,625,000</b>
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<b>Fund Balances at Beginning of Year (7/1/17)</b>	<b>53,366,036</b>		<b>53,366,036</b>
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<b>FUND BALANCES AT END OF YEAR</b>	<b>55,991,036</b>	<b>0</b>	<b>55,991,036</b>
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University of Massachusetts Biologic Laboratories

**Statement of Revenues, Expenditures and Other Changes  
For the Period July 1, 2018 Through June 30, 2019**

(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	32,400,000		32,400,000
Restricted Grants & Contracts	7,808,000		7,808,000
State Appropriations/DPH		516,000	516,000
Royalty Fees and Interest	18,796,000		18,796,000
Recovery of Indirect Costs	1,156,000		1,156,000
Other Income	(400,000)		(400,000)
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Total Revenue and Other Additions	59,760,000	516,000	60,276,000
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	20,299,000	390,000	20,689,000
Fringe Benefits	6,468,000	121,000	6,589,000
Supplies and Services	27,836,000	5,000	27,841,000
Depreciation	2,400,000	0	2,400,000
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Total Expenditures and Other Deductions	57,003,000	516,000	57,519,000
	<hr/>		
Net Increase/(Decrease) Before Transfers	2,757,000	0	2,757,000
Nonmandatory Transfers			
Transfers			
	<hr/>		
Total Transfers	0	0	0
	<hr/>		
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
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NET INCREASE(DECREASE) FOR THE YEAR	2,757,000		2,757,000
	<hr/>		
Fund Balances at Beginning of Year (7/1/18)	55,991,036		55,991,036
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FUND BALANCES AT END OF YEAR	58,748,036	0	58,748,036
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**University of Massachusetts Biologic Laboratories**  
**Statement of Revenues, Expenditures and Other Changes**  
**For the Period July 1, 2019 Through June 30, 2020**

(Unaudited)

	<u>CURRENT FUND</u>	<u>APPROPRIATED FUNDS</u>	<u>TOTAL</u>
<b>REVENUE AND OTHER ADDITIONS:</b>			
Product Sales	33,532,000		33,532,000
Restricted Grants & Contracts	7,808,000		7,808,000
State Appropriations/DPH		516,000	516,000
Royalty Fees and Interest	18,796,000		18,796,000
Recovery of Indirect Costs	1,156,000		1,156,000
Other Income	(400,000)		(400,000)
	<hr/>		
<b>Total Revenue and Other Additions</b>	<u>60,892,000</u>	<u>516,000</u>	<u>61,408,000</u>
<b>EXPENDITURES AND OTHER DEDUCTIONS:</b>			
Salaries	20,683,000	390,000	21,073,000
Fringe Benefits	6,590,000	121,000	6,711,000
Supplies and Services	28,252,000	5,000	28,257,000
Depreciation	2,472,000	0	2,472,000
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<b>Total Expenditures and Other Deductions</b>	<u>57,997,000</u>	<u>516,000</u>	<u>58,513,000</u>
<b>Net Increase/(Decrease) Before Transfers</b>	2,895,000	0	2,895,000
<b>Nonmandatory Transfers</b>			
Transfers			
	<hr/>		
<b>Total Transfers</b>	<u>0</u>	<u>0</u>	<u>0</u>
<b>Other Changes</b>			
Excess of Restricted Receipts over Transfers to Revenue			
<b>NET INCREASE(DECREASE) FOR THE YEAR</b>	2,895,000		2,895,000
<b>Fund Balances at Beginning of Year (7/1/19)</b>	<u>58,748,036</u>		<u>58,748,036</u>
<b>FUND BALANCES AT END OF YEAR</b>	<u>61,643,036</u>	<u>0</u>	<u>61,643,036</u>